

1 Plasma sterilization treatment of two Sterisafe®-sterile containers made of different materials (A: polyetherimide, B: polyphenylsulfone) in a plasma reactor.

PLASMA STERILIZATION FOR THERMOLABILE MATERIALS

Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB

Nobelstrasse 12
70569 Stuttgart | Germany

Contact

Dr. Michael Müller (Plasma technology)
Phone +49 711 970-4183
michael.mueller@igb.fraunhofer.de

Dr. Iris Trick (Mikrobiologie)
Phone +49 711 970-4217
iris.trick@igb.fraunhofer.de

www.igb.fraunhofer.de

Demands

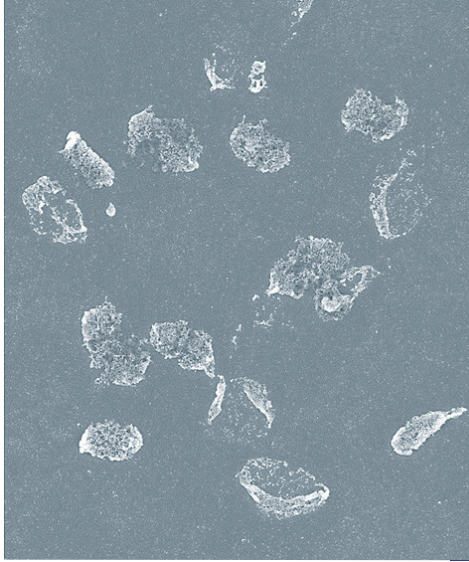
In traditional sterilization methods, microorganisms are inactivated through various physical or chemical agents such as heat, radiation or the influence of toxic gases. The choice of the sterilization method depends on the material composition, the objective of the treatment and the range of application. With thermolabile materials such as medical products or equipment in medical engineering, thermal sterilization processes are not suitable. Gas sterilization procedures using explosive, toxic or carcinogenic gases are not optimal as well because they require high safety standards. Sensitive materials can be even degraded or irreversibly damaged by reactive chemical compounds during the gas sterilization process.

Plasma sterilization – an alternative?

Plasmas are successfully used in technical etching and cleaning processes. The sterilizing action of low-temperature plasmas – inactivating microbial cells – offers a material-friendly alternative. In addition, the reactive particles in the plasma (excited molecules, radicals, ions accelerated in the electric field, and photons) remove organic contaminations such as microbial residues. The sterilizing gas mixtures are in fact produced directly in the plasma and no costly disposal of process media is necessary.

Process development

Scientists at the Fraunhofer IGB are working since several years on the development of plasma sterilization processes towards the industrial application level. Various operating



conditions and gas mixtures have been tested with respective diagnostic processes in a plasma reactor developed at Fraunhofer IGB.

Plasma inactivates microorganisms

We were able to show, that various types of highly resistant bacterial endospores are not able to survive in the plasma even within relatively short treatment times and that the temperature increases only very slightly. Even with a relatively low power in the range of W/cm^2 , the initial spore number in standardized samples with a defined number of spores (10^8) could be reduced by a factor of greater than 10^7 after just three minutes. Scanning electron microscope images show a significant degradation of the cell substance after such a plasma treatment.

Plasma degrades pyrogens

On one hand medicinal products and medical devices such as implant materials, surgery instruments, endoscopes and catheters have to be sterile, i.e. free of living bacteria. Furthermore, it has to be ensured that they are free of pyrogens, fever-inducing residues of fungi or bacteria which can cause blood poisoning if they enter a patient's bloodstream. Beside the sterilizing effect, an appropriate plasma treatment leads to degradation of pyrogenic residues and components. Using suitable methods for the detection of pyrogens we could verify that in contrast to steam sterilization the plasma inactivation of the microbial cells is accompanied by a significant depyrogenization of the materials.

Services

Microbiological processes

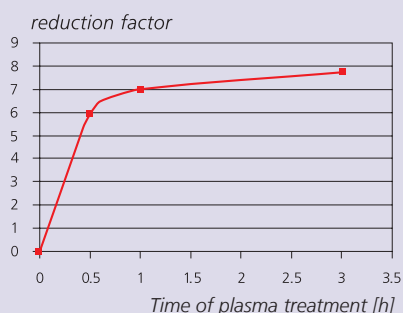
- Development of suitable biological testing methods
- Selection and supply of biological indicators
- Evaluation of the sterilization results with biological methods
- Detection of pyrogens

Plasma chemistry and process technology

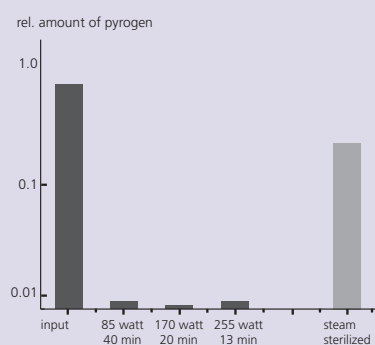
- Development of sterilization methods
- Plasma diagnostics
- Surface diagnostics
- Evaluation of the treatment under material-relevant aspects

Sterisafe® – Product of Savuna GmbH, Augsburg.

Reduction of spores (*Bacillus atrophaeus*) during plasma sterilization



Depyrogenation of material (*Bacillus atrophaeus*)



2 *Bacillus atrophaeus*, left: before plasma sterilization; right: degraded substance after plasma sterilization.